

§ 112, second paragraph. Applicants also acknowledge the Office's indication of the allowability of Claim 36 if rewritten in independent form.

## **II. Rejection Under 35 U.S.C. § 103**

The Office has maintained the rejection of claims 30-34 and 37-71 under 35 U.S.C. §103(a) over Dubief et al. (U.S. Patent No. 5,700,456) ("Dubief") in view of the International Cosmetic Ingredient Dictionary ("ICID"). Applicants respectfully traverse the rejection on the basis that a prima facie case of obviousness has yet to be established.

### **A. The Office's Position**

Independent claim 30 is drawn to a composition for the oxidation dyeing of keratin fibers comprising at least one oxidation dye precursor and at least one nonionic amphiphilic polymer comprising at least one fatty chain and at least one hydrophilic unit, said at least one nonionic amphiphilic polymer being chosen from: (1) celluloses modified with groups containing at least one fatty chain, and (2) hydroxypropyl guar modified with groups containing at least one fatty chain.

The Office argues that Dubief teaches a hair treatment composition which "may also contain thickening agents like NATROSOL PLUS" and "may also be used for the dyeing of keratinous fibers such as hair, in which case they contain oxidation dyes and/or direct dyes." Office Action dated October 24, 2001, page 3. The Office further points to Example 6 of Dubief, which relates to an oxidation dyeing composition in cream (thickened) form and contains an oxidation dye precursor (p-phenylenediamine). The Office relies on ICID simply for its teaching that NATROSOL PLUS is cetyl-modified hydroxyethyl cellulose. In view of the above, the Office concludes that one of ordinary

skill in the art would have been motivated to incorporate cetyl hydroxyethylcellulose into the composition of Dubief for use in oxidation dyeing of keratinous fibers. See, e.g., Final Office Action dated April 10, 2002, at pages 3-4.

**B. No Prima Facie Case of Obviousness has been Established**

Applicants disagree with the Office. For a *prima facie* case of obviousness to be established, the Office must point to, among other things, evidence of motivation to modify or combine reference teachings and a reasonable expectation of success if the modification or combination is made. M.P.E.P. §2143 (8<sup>th</sup> ed. 2001). The Federal Circuit has required that this evidence of motivation be "clear and particular." *In re Dembiczak*, 175 F.3d 994, 999 (Fed. Cir. 1999). No such evidence has been produced here, and accordingly no *prima facie* case has been made.

**1. The passages of Dubief relied on by the Office do not provide motivation to make the proposed modification to the reference.**

Although the Office's assertion that the compositions of Dubief can be used for oxidative hair dyeing is technically correct, Applicants submit that Dubief's compositions are useful for many purposes, generally referred to as the treatment and protection of hair, only one of which is the dyeing of hair. See column 9, lines 15-30. In the final Office Action, the Office points to claim 17 of Dubief for the supposed disclosure of an oxidation dyeing composition for hair. Claim 17 of Dubief is drawn to a process for dyeing hair using the composition of claim 1 of Dubief. However, this claim is not directed specifically to an oxidative hair dye. The claims, however, constitute a legal description; they do not constitute prior art. See *In re Benno*, 768 F.2d 1340 (Fed. Cir. 1985).

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Moreover, Dubief discloses at column 9, lines 19-21, that his hair dyes may contain oxidation dyes **and/or direct dyes**. Thickening agents are disclosed as optional additional ingredients. Taking these aspects of Dubief into account, it can hardly be said that there is a "clear and particular" suggestion in the cited art to modify Dubief by adding cetyl-modified hydroxyethyl cellulose (disclosed by ICID to be NATROSOL PLUS) to obtain the presently claimed invention as proposed by the Office.

Further, with respect to the thickening agents, the ingredients for Dubief's compositions are disclosed via a series of laundry lists. NATROSOL PLUS appears in one such extensive laundry list, cited by the Office and drawn to thickening agents, at column 8, lines 36-47. The list includes ten genera and ten named species. There is nothing in Dubief that would have motivated one of ordinary skill to use any particular thickener with any given composition, let alone an oxidation dye composition, and, even if a thickener were included, there would not be a reasonable possibility that the thickener could be added to give a successful **hair dye** product, let alone an **oxidative** hair dye product.

At most, Dubief suggests that if one needed to thicken a given composition for one of the many uses disclosed by Dubief, then a thickener at column 8 could be tried to see if it worked in the specific composition in light of the other ingredients and the intended use. As the Office knows, "obvious to try" is not the standard against which obviousness is measured. *See In re O'Farrell*, 853 F.2d 894, 902 (Fed. Cir. 1988).

Finally, the Office relies on Example 6 of Dubief as teaching a thickened oxidative hair dyeing composition. The Office acknowledges that the nonionic, amphiphilic, modified hydroxyethyl cellulose thickening agent NATROSOL PLUS is not

included in Example 6, but contends that “[t]he fact remains that the compositions of Dubief, which can also be used for the oxidation dyeing of keratinous fibers (see col. 9, lines 18-20) can contain thickening agents such as NATROSOL PLUS (see col. 8, lines 36-45), which is cetyl hydroxyethylcellulose.” Final Office Action at page 3. The Office concludes that “with these teachings, a person of ordinary skill in the art would be motivated to incorporate cetyl hydroxyethylcellulose into the composition of Dubief for use in oxidation dyeing of keratin fibers.” *Id.* at pages 3-4.

The Federal Circuit has held that the mere fact that a reference can be modified does not render the modification obvious unless the prior art suggests the desirability of the modification. *In re Mills*, 916 F.2d 680, 682 (Fed. Cir. 1990); MPEP § 2143.01 (emphasis in original). Under this reasoning, the sections of Dubief relied upon do not support the Office’s ultimate conclusion. The Office has merely assumed, rather than established, that which is necessary for a *prima facie* case of obviousness; i.e. a specific motivation to modify or combine the teachings of the references with a basis in the references such that one skilled in the art would have had a reasonable expectation of success in making such a modification or combination. The rejection should be withdrawn for this reason alone.

**2. Dubief teaches away from the presently claimed invention**

In addition to the lack of evidence in the references to support a “clear and particular” suggestion for their combination, Dubief provides no desirability or guidance for the combination proposed by the Office, and in fact teaches away from such a combination. Dubief’s only dyeing example (Example 6) is already in thickened cream form. Dubief, while disclosing thickeners as possible ingredients for its various

products, teaches by example that its oxidative dyeing compositions **do not require additional thickening agents**. As such, one skilled in the art would have been discouraged from adding any thickener to an oxidative dyeing composition. Therefore, there is no motivation in the reference to add any thickener, let alone a *specific* thickener, to such a composition.

Because the only specific suggestion in Dubief (with respect to oxidative dyeing compositions) is **not** to add a thickening agent, one of ordinary skill in the art would not have been motivated to use any thickening agent, let alone NATROSOL PLUS. See *Winner Int'l. Royalty Corp. v. Wang*, 202 F.3d 1340, 1349, 53 U.S.P.Q.2d 1580 (Fed. Cir. 2000). The lack of any need or reason to add any thickener would not have motivated one skilled in the art to add any thickener, let alone NATROSOL PLUS.

For this additional reason, the Office has not established a *prima facie* case of obviousness.

**B. *Even if there were motivation to add NATROSOL PLUS to a hair dyeing composition, there would not have been a reasonable expectation of success in doing so***

As argued above, there is simply no support for the Examiner's attempt to draw from different parts of the Dubief reference in an attempt to modify the examples therein. One of ordinary skill in the art would simply not have been motivated to make all the necessary choices from Dubief's disclosure suggested by the Examiner. Further, even if there were motivation in Dubief for the addition of NATROSOL PLUS to an oxidative hair dyeing composition, Dubief does not provide any basis for a reasonable expectation of success if such a modification were made. In fact, those skilled in the art recognize that not all thickening agents are equivalent and that it takes considerable

effort to find a thickener that works consistently and successfully in any given oxidative dyeing system.

Specifically, those skilled in the art know that the selection of an agent capable of properly thickening an oxidative hair dye composition is an unpredictable business. That this unpredictability was known to those skilled in the art at the time of the Applicants' invention is graphically illustrated by the Pohl application and the Cohen and Casperson patents, which are already of record<sup>1</sup> and will be discussed in detail below. In view of the knowledge of one of ordinary skill in the art—as demonstrated in the Pohl application and the Cohen and Casperson patents—regarding the unpredictability of selecting thickening agents associated with oxidative hair dyes, there would have been no reasonable probability of success at the time of Applicants' invention, to utilize the thickening agents of the claimed invention in Dubief's oxidative hair dye compositions.

1. **The Pohl Application**

The Pohl application<sup>2</sup> articulates the problem of finding a thickener for hair treatment formulations that is stable in a hydrogen peroxide oxidizing composition. Pohl reported that the thickener Acrysol ICS, an acrylic anionic polymer, was surprisingly stable when added to hydrogen peroxide and was the key ingredient of the oxidizing composition component of oxidative hair dye compositions. See Pohl patent, col. 3, lines 6-11. According to Pohl's representations to the PTO, Acrysol-ICS was the one acrylic thickener that was stable, *i.e.*, the only acrylic thickener that worked. See Pohl

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1 The Cohen and Casperson patents are of record in the present application. They were submitted in an IDS dated October 10, 2001.

2 The Pohl application, EP 0 241 707, was published October 21, 1997. The U.S. equivalent to the Pohl application, U.S. Patent No. 4,776,855 (the "Pohl patent"), issued on October 11, 1988, and was reissued as Re. 33786 on January 7, 1992. The Pohl patent, and its reissue patent were submitted in an IDS for this case dated October 10, 2001.

Patent prosecution history,<sup>3</sup> Amendment dated November 11, 1986. (Acrysol ICS is an **anionic** polymer and is presently supplied by Rohm and Haas under the trademark Aculyn 22. See EP 0 875 237 A2, p.2, lines 50-51; U.S. Patent No. 5,376,146.)

While the Pohl application initially disclosed a genus of potential polymers, by the time of Applicants' invention, the skilled artisan knew that not all of the polymers of the Pohl genus worked. During the reissue of the Pohl patent, Pohl confirmed this by urging that Acrysol-ICS was the only polymer that worked.

Therefore, considering the teachings of Pohl, the skilled artisan would not have had any reasonable expectation that any polymer other than Acrysol-ICS would have been successful as a thickener in oxidative dye compositions. This lack of reasonable expectation of success was subsequently confirmed by others, as discussed below.

## **2. The Cohen Patent**

Cohen<sup>4</sup> heavily emphasizes the unpredictability associated with oxidative hair dyes, setting forth various bases for this unpredictability throughout the patent. For example, Cohen teaches, see col. 1, lines 17-60, that oxidative dyes having a two-part system, as recited therein, involve a delicate balance designed to satisfy several conditions:

- (1) Stability of the formulation to ensure a reasonable shelf life;

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3 The prosecution history of the Pohl patent has been made of record in the prosecution history of Applicants' parent U.S. Patent No. 6,010,541 ("the '541 patent"), and it became publicly available as of the issuance date of the Pohl patent. In other words, the entire prosecution history is just as much a teaching in the art as of that date as is the patent itself.

4 Cohen et al., U.S. Patent No. 5,393,305, issued February 28, 1995 ("Cohen").

- (2) Rheological properties resulting from mixing the lotion and developer that allow ready distribution of product without experiencing dripping and running;
- (3) Rapid diffusion of the dye precursors from the dye mixture into the hair fiber;
- (4) Ready rinseability from the hair with water;
- (5) Inclusion of functionally effective conditioning agents;
- (6) Comparable viscosities of the lotion and developer to facilitate mixing; and
- (7) Rapid dyeing effect.

Cohen provides a lengthy discussion of the defects of the prior art, including a discussion of the Pohl Reissue patent referred to above. See col. 3, lines 13-29. Like Pohl, Cohen struggled with the issue of finding a suitable polymer for use in a developer containing a peroxide oxidizing agent and for assisting in the formation of a gel. See col. 10, lines 26-31. Cohen describes his highly specific anionic polymer as typically a copolymer of acrylic acid and acrylic esters such as those sold under the trademark Aculyn 22 and 33 by Rohm and Haas. See col. 10, lines 38-42. Pohl's anionic Acrysol-ICS thus apparently falls within the genus of Aculyn compounds disclosed by Cohen. Cohen, however, uses only Aculyn 33 in his examples.

In attempting to remedy the defects of the prior art, Cohen focuses on the importance, *i.e.*, the unpredictability, of his selection of the anionic polymer for use in



the developer as a gel former. See col. 8, lines 59-61 and col. 10, lines 26-31, respectively, where Cohen stated:

The selection of the cationic polymer for use in the lotion of this invention is **critical** as is the selection of the anionic polymer for use in the developer.

. . . .

An **important** aspect of the practice of this invention is the selection of the anionic polymer for use in the developer. It should be stable to the peroxide oxidant, insoluble in the developer and, when the developer is mixed with the lotion, assist in the formation of a gel in which the anionic polymer is soluble. [Emphasis added.]

To highlight further Cohen's emphasis on the "importance" and "criticality" of selection of the anionic polymer as a gel former in the oxidative dye composition, Applicants refer to statements made in the prosecution history of Cohen,<sup>5</sup> which as explained above, is prior art as of the issue date of the Cohen patent and thus prior to the effective filing date of the present application.

In that prosecution history, Cohen underscored the unpredictability involved in selecting anionic polymers to be used as gel formers in his compositions. For example, Cohen stated that those of skill in the art knew to incorporate water-insoluble anionic polymers into the developer component to produce a thickening effect when the developer was added to the lotion. Experience, however, demonstrated that developers

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5 The prosecution history of the Cohen patent was made of record in the prosecution history of the '541 patent and it became publicly available as of the issuance date of the Cohen patent. In other words, the entire prosecution history is just as much a teaching in the art as of that date as is the patent itself. If the Office wishes Applicants to submit another copy of this prosecution history in the present case, as well as that of Casperson, discussed below, please notify the undersigned. The same is true for portions of the Pohl file history cited herein.

containing such anionic polymers were difficult to formulate because the viscosity of the resulting mixture was not readily controllable:

It has been known to thicken hair lotion/developer mixtures by the use of water-soluble anionic polymers. However, when these thickeners are incorporated in the alkaline dye lotion, they produce a thick cream or gel which is difficult to mix with the aqueous hydrogen peroxide solution. Furthermore, it has been observed that these water-soluble polymers are not stable in aqueous hydrogen peroxide solutions.

It has also been known to incorporate water-insoluble anionic polymers into the developer component. Such polymers produce a thickening effect when the developer is added to the alkaline dye lotion. However, experience has shown that developers containing such anionic polymers are difficult to formulate because the viscosity of the resulting mixture is not readily controllable. Additionally, the use of these or any other anionic polymers with cationic compounds is normally disadvantageous because the anionic polymers tend to deactivate the cationic compounds by complexation.

Response dated August 4, 1994, at 16-17.

Cohen thus highlighted the delicate balance involved with his invention by teaching away from the use of the specific polymers of the prior art or "any other anionic polymers." Continuing, Cohen emphasized how surprising it was that his invention, using anionic copolymers of acrylic acid and acrylic acid esters, obtained the properties disclosed:

However, Applicants have overcome the aforementioned problems by their discovery of a compatible two-part oxidative hair dye composition which produces a suitably viscous gel upon mixture, wherein the first part comprises a cationic polymer and the second part comprises an anionic polymer. It has been **surprisingly** found that this hair dye composition provides superior, durable conditioning and improved rinseability, as well as greater viscosity control over the mixture. Moreover, it has been **surprisingly** found

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that the mixture of cationic polymer and anionic polymer of the present invention is a notable improvement over the prior art, including the cited Pohl and Sokol references, either taken alone or in combination.

*Id.* at 17; emphasis added.

As mentioned, the Pohl reference referred to by Cohen is the very Pohl reference discussed above. Cohen further emphasized in the file history the noninterchangeability of anionic polymers in general with the specific water-insoluble anionic acrylic polymers he found useful, *i.e.*, the anionic copolymers of acrylic acid and acrylic acid esters. Cohen took the position that the primary reference applied against his claims, the Pohl patent (notably, Pohl is a co-inventor of the Cohen patent), touted a specific anionic polymer, Aculyn 22 (Acrysol-ICS), as a key ingredient. *Id.*

To be sure, Cohen originally taught, as discussed above, that Aculyn polymers in general were useful in his invention:

Typically useful polymers employed in the invention include copolymers of acrylic acid and acrylic esters such as those sold under the trade mark Aculyn by Rohm and Haas Company. These polymers are insoluble in the developer solution and form a gel when the developer is added to the alkaline dye lotion.

Cohen Specification, col. 10, lines 32-37.

In the specification, however, Cohen reports tests using only Aculyn 33 in the developer. See col. 12, Examples 1-10. His subsequent experience demonstrated that not even all Aculyn copolymers were useful. Cohen discovered that his composition was unpredictable and that Aculyn 22, the only polymer that Pohl had found useful, itself failed to control viscosity even over relatively minor concentration changes.

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As evidentiary support for the unacceptability of Aculyn 22, Cohen filed, along with the August 1994 response, the declaration of Dr. Stanley Pohl himself. Dr. Pohl compared the viscosity characteristics of Aculyn 22 against the preferred anionic polymer of Cohen, Aculyn 33, and determined that the viscosity of Aculyn 22 is unacceptably much more volatile and sensitive to concentration changes.

Accordingly, Cohen amended his main claim to exclude Aculyn 22, and added claims directed specifically to Aculyn 33. At page 19 of the associated amendment, Cohen urged that Aculyn 22 is "very different" from Aculyn 33:

For the foregoing reasons, Applicants believe that the superiority of their claimed anionic polymer clearly supports the patentability of their invention. To this end, Applicants have specifically narrowed their main claim to define the anionic polymer so that it does not include within its scope Aculyn 22, which as described in the CTFA, is very different from the CTFA definition of Aculyn 33.

Thus, Cohen reinforces the unpredictability of the subject matter of Pohl. Indeed, Cohen emphasizes that this unpredictability comes, in part, from the delicate balance of the seven conditions that must be considered when designing oxidative hair dyes. In light of this well-recognized unpredictability of anionic polymers as thickeners in the oxidative dyeing art, the mere mention in Dubief of the nonionic polymer NATROSOL PLUS as a potential thickener in no way provides a reasonable expectation that, on the off-chance that this particular nonionic thickener was added to an oxidative hair dyeing composition falling within the scope of Dubief, a successful composition would result.

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### 3. *The Casperson Patent*

The disclosure of Casperson<sup>6</sup> is strikingly similar to that of Cohen; the same assignee, Bristol-Myers Squibb Co., filed both on the same day, August 26, 1993. Just like Cohen, Casperson teaches the unpredictability associated with oxidative hair dyes, setting forth various bases for this unpredictability throughout his patent. The specification provides a discussion identical to Cohen relating to the fact that two-part oxidative dyes involve a delicate balance designed to satisfy several conditions. See col. 1, lines 16-59. Casperson was also looking to discover developers and lotions that can be readily formed into a gelled mixture. See col. 3, lines 35-39.

Like Cohen, Casperson engages in a lengthy discussion of the defects of the prior art, also including a discussion of the Pohl Reissue. See col. 3, lines 10-26. Following this discussion, Casperson proposes to remedy those defects by providing a two part oxidative hair-coloring composition including a substantially water-insoluble anionic acrylic polymer. See col. 3, lines 47-62. Just like Cohen, Casperson focuses on the importance of the selection of the anionic polymer for use in the developer:

An important aspect of the practice of this invention is the selection of the anionic polymer for use in the developer. As indicated above, some anionic polymers including certain acrylate polymers tend to deactivate quaternary ammonium compounds by forming complexes. See col. 9, lines 63-68.

Casperson points out that certain anionic polymers avoid these defects.

Casperson refers to certain polymers available and mentions both Aculyn 22 (used in the Pohl patent as described above) and 33 (used in the Cohen patent as described

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6 Casperson et al., U.S. Patent No. 5,376,146, issued December 27, 1994 ("Casperson").

above). See col. 10, lines 22-29. In other words, in this particular invention of Casperson, Aculyn 22 could be used, but in the invention of Cohen, filed the same day by the same assignee, Aculyn 22 was inappropriate. This underscores the unpredictability of polymeric thickeners known to those skilled in the oxidative dyeing arts.

In support of their position, Applicants refer to the prosecution history of Casperson,<sup>7</sup> where Casperson further underscored the unpredictability involved in selecting polymers to be used in his oxidative dye compositions. In a March 7, 1994, Office Action, the Office argued that it would have been obvious to substitute at least partially an anionic polymer taught in the very reference to Pohl discussed above for an anionic polymer taught in a reference to Yoshihara to obtain the Casperson invention.

In response, Casperson emphasized the particular importance of the specific ingredients of his two part composition:

The present invention comprises a two-part, aqueous, oxidative hair coloring composition wherein the two parts are mixed with each other shortly before use to form a gel . . . . It has been discovered that this two-part composition, particularly the combination of the linear quat and the anionic polymer which are kept separate until mixed before use, produces a hair dye having excellent rheological properties.

Amendment dated June 7, 1994, at 13-14. Casperson pointed out how his specific combination surprisingly achieved the desired coloring effect:

The present invention provides an environment wherein lotions and developers can be readily and easily

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<sup>7</sup> The prosecution history became publicly available as of the December 27, 1994, issue date of the Casperson patent, and is thus also part of the prior art. The prosecution history of the Casperson patent was made of record in the prosecution history of the '541 patent and it became publicly available as of the issuance date of the Casperson patent. In other words, the entire prosecution history is just as much a teaching in the art as of that date as is the patent itself.

formed into a gelled mixture having an appropriate viscosity to remain on the hair for a sufficient period of time to achieve the desired hair coloring effect. This is particularly surprising and unexpected in view of the prior art wherein a high level of surfactants and organic solvents are required to provide a thin dye lotion which, upon mixture with a highly aqueous developer solution of an oxidizing agent, forms a dye mixture with an appropriate gel-like consistency.

*Id.* at 14.

Casperson made this surprising breakthrough based on experiments utilizing only either Aculyn 22 or Aculyn 33, even though Cohen, in his invention, was unable to use Aculyn 22. Casperson, therefore, teaches those skilled in the art that it is very surprising that his two-part composition was effective. Given this unpredictability, Casperson admitted that his invention would not extend to any other anionic polymer:

It has also been known to incorporate water-insoluble anionic polymers into the developer component. Such polymers produce a thickening effect when the developer is added to the alkaline dye lotion. Unfortunately, the use of these **or any other anionic polymers** with quaternary compounds is normally disadvantageous because the anionic polymers tend to deactivate the quaternary conditioning compounds by complexation. Additionally, experience has shown that developers containing anionic polymers are difficult to formulate in that the viscosity of the resulting mixture is not readily controllable.

*Id.* at 15; emphasis added.

Thus, Casperson reinforces the unpredictability of the subject matter of both Cohen and Pohl. Casperson also thus specifically reinforces the conclusions that in light of the well-recognized unpredictability in the oxidative dyeing art, the mere mention in Dubief that certain polymers (such as nonionic NATROSOL PLUS) are optionally used in compositions that in different embodiments may be dyeing compositions in no way provides a reasonable expectation of success.

4. **Pohl, Casperson, and Cohen show the unpredictability of associative polymers generally**

Although the Pohl application, Cohen, and Casperson discuss the use of **anionic** associative polymers, and the present claims recite **nonionic** associative polymers, their disclosures demonstrate the broader proposition that not all polymers are equivalent. Moreover, Dubief himself teaches the equivalence (in his disclosure) of nonionic and anionic associative polymers by failing to distinguish between them. See column 8, lines 43-45, where Dubief recites only “associative thickeners bearing fatty chains of the natural type.” Both anionic and nonionic associative polymers are covered by this broad description. Thus, Pohl, Cohen, and Casperson underscore Applicants’ position that one of skill in the art would not have had a reasonable expectation of success by using nonionic associative thickening polymers in an oxidative hair dyeing composition of Dubief because of the unpredictability associated with the selection of thickeners.

This known unpredictability in selecting thickeners for oxidative hair dye compositions combined with the lack of motivation to thicken Dubief’s oxidative hair dyeing compositions would not engender an expectation of success if one must choose ingredients randomly from laundry lists, such as those of Dubief. Indeed, this unpredictability would cause one not to know what to expect by adding a cetyl-modified hydroxyethyl cellulose thickener, or any thickener, to the already thick composition of Dubief’s example 6. Not knowing what to expect is not a reasonable expectation of success.



Accordingly, Applicants submit that the claimed invention is not obvious over the teachings of Dubief in view of ICID. Reconsideration and withdrawal of the rejection are respectfully requested.

### III. CONCLUSION


In view of the foregoing remarks, Applicants respectfully request the reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this paper and charge any additional required fees to our deposit account 06-0916

Respectfully submitted,

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